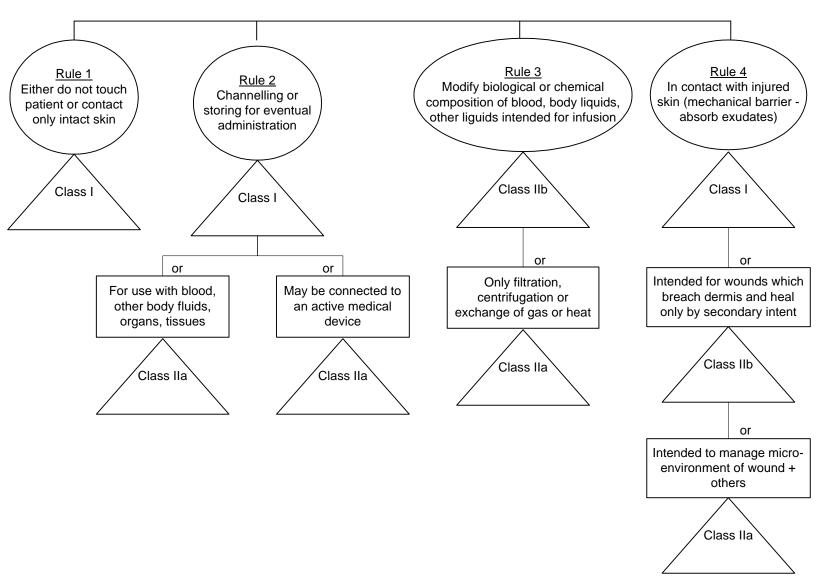
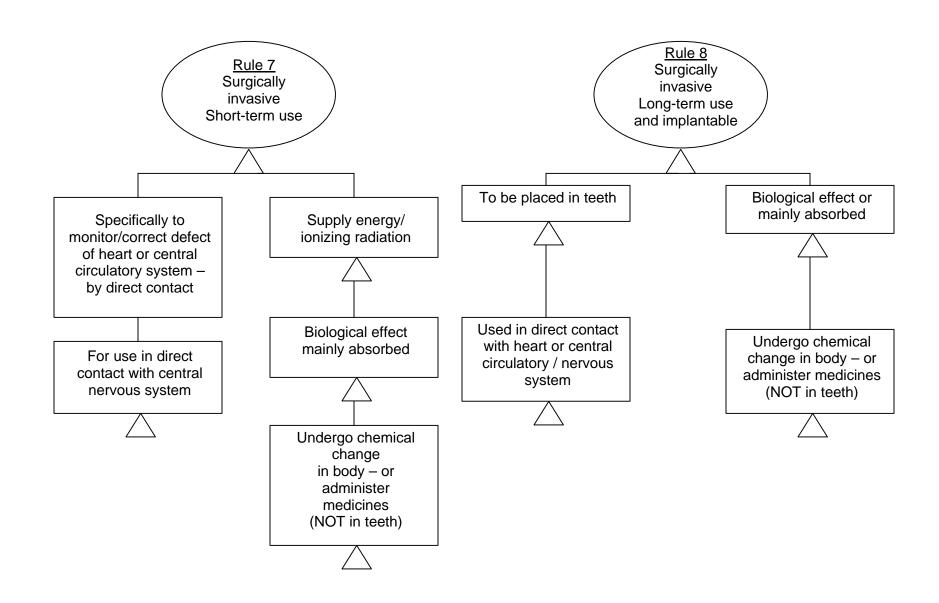
Medical devices classification guidance chart

Source: European Commission MEDDEV 2.4/1-rev.6, December 1999

NON INVASIVE DEVICES



INVASIVE DEVICES Rule 5 Rule 6 Invasive in body Surgically invasive orifice or stom a - transient use (not surgically) o r Class Ila Connected to an Long term Transient use Short term active medical use use device of Class IIa Supply energy/ or higher Diagnose/control o r ionizing radiation Class - defect of heart/ Class central circulation system Class lla IIb Class Ilb Class Class III lla Reusable surgical or o r o r instrument If only in oral If only in oral Biological effect cavity, ear canal cavity, ear canal -mainly absorbed Class I or nasal cavity or nasal cavity Class Ilb Class Class o r lla System to administer medicines - potentially hazardous Class Ilb



ACTIVE DEVICES

